4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. FDA-2012-F-0031]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is amending the food additive regulations to no longer provide for the use of polycarbonate (PC) resins in infant feeding bottles (baby bottles) and spill-proof cups, including their closures and lids, designed to help train babies and toddlers to drink from cups (sippy cups) because these uses have been abandoned. The action is in response to a petition filed by the American Chemistry Council.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either electronic or written objections and requests for a hearing by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section VIII of this document for information on the filing of objections.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing, identified by Docket No. FDA-2012-F-0031, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- FAX: 301-827-6870.
- Mail/Hand delivery/Courier (for paper or CD-ROM submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-F-0031 for this rulemaking. All objections received will be posted without change to http://www.regulations.gov, including any personal information provided. For detailed instructions on submitting comments, see the section VIII. Objections in the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or objections received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Vanee Komolprasert,

Center for Food Safety and Applied Nutrition (HFS-275),

Food and Drug Administration,

5100 Paint Branch Pkwy.,

College Park, MD 20740-3835,

240-402-1217.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of February 17, 2012 (77 FR 9608), FDA announced that a food additive petition (FAP 1B4783) had been filed by the American Chemistry Council (ACC), 700 Second St. N.E., Washington, DC 20002. The petition proposed to amend the food additive regulations in § 177.1580 (21 CFR 177.1580) to no longer provide for the use of PC resins in baby bottles and sippy cups because these uses have been abandoned. PC resins are formed by the condensation of 4,4'-isopropylenediphenol (i.e., Bisphenol A (BPA)), and carbonyl chloride or diphenyl carbonate. PC resins may be safely used as articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, in accordance with the prescribed conditions of § 177.1580.

II. Evaluation of Abandonment

Under section 409(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(i)), FDA "shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations." FDA's regulations specific to administrative actions for food additives provide as follows: "The Commissioner, on his own initiative or on the petition of any interested person, pursuant to part 10 of this chapter, may propose the issuance of a regulation amending or repealing a regulation pertaining to a food additive or granting or repealing an exception for such additive." (§ 171.130(a) (21 CFR 171.130(a))). These regulations further provide: "Any such petition shall include an assertion of facts, supported by data, showing that new information exists with respect to the food additive or that new uses have been developed or old uses abandoned, that

new data are available as to toxicity of the chemical, or that experience with the existing regulation or exemption may justify its amendment or appeal. New data shall be furnished in the form specified in §§ 171.1 and 171.100 for submitting petitions." (§ 171.130(b)). Under these regulations, a petitioner may propose that FDA amend a food additive regulation if the petitioner can demonstrate that there are "old uses abandoned" for the relevant food additive. Such abandonment must be complete for any intended uses in the U.S. market. While section 409 of the FD&C Act and § 171.130 also provide for amending or revoking a food additive regulation based on safety, an amendment or revocation based on abandonment is not based on safety, but is based on the fact that regulatory authorization is no longer necessary for the use of the food additive because that use has been permanently and completely abandoned.

Abandonment may be based on the abandonment of certain authorized food additive uses for a substance (e.g., if a substance is no longer used in certain product categories) or on the abandonment of all authorized food additive uses of a substance (e.g., if a substance is no longer being manufactured). If a petition seeks an amendment to a food additive regulation based on the abandonment of certain uses of the food additive, such uses must be adequately defined so that both the scope of the abandonment and any amendment to the food additive regulation are clear.

The ACC petition contained public information and information collected from companies that produce PC resins to support the claim that baby bottles and sippy cups manufactured from PC resins are no longer being introduced into the U.S. market and that manufacturers of baby bottles and sippy cups have abandoned the use of PC resins in making these products. Specifically, the petition contained the results of an industry poll showing that the PC resin manufacturers, which represent over 97 percent of worldwide PC resin production

capacity, are no longer, to their knowledge, selling PC resins to be used in the manufacture of baby bottles and sippy cups intended for import into the United States or sale in the U.S. market.

III. Comments on the Filing Notice

The Agency provided 60 days for comments on the filing notice. FDA received six distinct comments from individuals and consumer groups (FDA received seven comments total, but one represented a corrected version of a comment submitted earlier). Three of the six comments exclusively addressed the safety of BPA in food, two of the comments addressed both safety and abandonment, while one comment addressed only abandonment. While none of these comments included any information to indicate that the use of BPA-based PC resins in the manufacture of baby bottles and sippy cups has not been completely and permanently abandoned, or to indicate that these uses were not adequately defined, these comments raised six main issues, discussed further in this document.

A. The Safety of BPA

As indicated in the filing notice (77 FR 9608 at 9609), because the petition was based on an assertion of abandonment, the Agency did not request comments on the safety of the use of PC resins in baby bottles and sippy cups. Such safety information is not relevant to abandonment and, therefore, any comments addressing the safety of PC resins were not considered in the Agency's evaluation of this petition. Separate from FDA's consideration of this petition, FDA is actively assessing the safety of BPA (see 75 FR 17145, April 5, 2010; see also http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm).

B. Whether the Subject Uses Are Adequately Defined

1. Baby Bottles

(Comment 1) One comment stated that the Agency did not offer additional description or clarification of the term "baby bottles," which was defined by ACC as "infant feeding bottles." The comment stated that this definition failed to identify the full spectrum of beverage containers from which infants, toddlers, and children consume beverages.

(Response) The Agency has concluded that the term infant feeding bottle (baby bottle) adequately defines the specific use of PC resins that is the subject of the proposed action so that both the scope of the abandonment and this amendment to the food additive regulation are clear. FDA agrees that this term does not cover the full spectrum of beverage containers from which infants, toddlers, and children consume beverages. However, this spectrum of beverage containers was not the scope of the petition. Instead, the petition was limited to the use of PC resins in baby bottles and sippy cups. FDA concludes that the terms "baby bottle" and "infant feeding bottle" are generally recognized by both the general public and the regulated industry and adequately define this use of PC resins addressed by the petition.

2. Sippy Cups

(Comment 2) The petition defined "sippy cup" as a spill-proof cup designed to help train babies to drink from cups. As stated in the filing notice (77 FR 9608 at 9609), for the purposes of this petition, FDA more specifically considers "sippy cup" to mean a spill-proof cup, including its closures and lids, designed to train babies or toddlers to drink from cups. FDA specifically requested comment on whether this use of PC resins is adequately defined. Two of the comments expressed the opinion that the term "sippy cup" is narrow or not inclusive of the different types of bottles and cups used by small children and toddlers, and defining sippy cups as cups that are spill-resistant would not cover the use of PC resins in toddler cups (such as drinking cups without a lid) that do not have this feature. One comment recommended that the

term "designed for" be clarified to include both functionality (e.g., spill-resistant) and aesthetics (e.g., anything with cartoon characters) in order to cover a broader category of products. Another comment recommended that the definition of "sippy cup" be expanded to include all cups rated for the target age group. No comments stated that this particular use of PC resins was not adequately defined.

(Response) The Agency has determined that the functionality of a spill-resistant cup is the critical factor in defining the particular use of PC resins that the petition asserted has been permanently and completely abandoned. The petition asserted that the use of PC resins in spill-proof cups has been abandoned. Because the scope of the petition was limited to functionality, and did not address aesthetics, FDA concludes that the functionality of spill resistance is the defining feature of a "sippy cup" as contemplated by the petition, and about which FDA requested comment.

The Agency has concluded that the phrase "spill proof cups, including their closures and lids, designed to help train babies or toddlers to drink from cups (sippy cups)" adequately defines the specific use of PC resins that is the subject of the proposed action and is generally recognized by the regulated industry and the public. The comments that addressed the term "sippy cup" did not assert that this term is unclear to consumers or industry, or that this use of PC resins is not adequately defined; instead, the comments opined that any action taken by FDA should address beverage containers used by children that are beyond the scope of these terms. FDA agrees that these terms do not cover the full spectrum of beverage containers from which infants, toddlers, and children consume beverages. However, this spectrum of beverage containers was not the scope of the petition. Instead, the petition was limited to specific uses of PC resins.

C. The Scope of the Uses of PC Resins Addressed by the Petition

(Comment 3) Two comments recommended that the scope of any action taken by FDA in response to ACC's petition include other products that an infant or toddler may regularly put in its mouth (e.g., pacifiers, teethers, tableware) or that may come in contact with breast milk (e.g., breast pump, pumping supplies, breast milk storage kits).

(Response) The Agency has concluded that it is not appropriate, in this amendment to the food additive regulations, to address any uses of PC resins beyond those specified in ACC's petition, for the following reasons:

- The suggested products are beyond the scope of the uses as described in the petition, about which the petition provided detailed evidence, and about which FDA requested comment; and
- No comments received by FDA provided specific information to demonstrate that any additional uses of PC resins have been completely and permanently abandoned.

D. Whether the Subject Uses Have Been Abandoned

(Comment 4) One comment expressed the opinion that PC resins are still used worldwide in the manufacture of plastics products and, although the current manufacturers of sippy cups do not currently use these resins, a new producer may still choose to use these PC resins to make plastic products. Accordingly, the comment asserts that removing these uses of PC resins from the food additive regulations leaves the opportunity for these uses of BPA to go "unchecked."

(Response) The Agency does not agree with this comment. First, the petition provided evidence that the use of PC resins in the manufacture of baby bottles and sippy cups has been permanently and completely abandoned, and FDA did not receive any comments demonstrating that these uses have not been abandoned. The comment addressed uses of PC resins that are beyond the scope of the petition and this action. A food is considered to be adulterated if it

contains an unapproved food additive (see section 409 of the FD&C Act). The amendment to § 177.1580 means that FDA's regulations no longer provide for the use of PC resins in baby bottles and sippy cups.

E. Labeling of BPA Containing Materials

(Comment 5) One comment asserted that because FDA does not require that manufacturers identify the presence of BPA-containing materials in their labeling, the general public is defenseless to counter industry assertions about the abandonment (i.e., the general public has no way of knowing whether industry has in fact abandoned certain uses of BPA-containing materials or whether certain products contain BPA), and recommended that FDA require labeling of all food contact materials that contain BPA.

(Response) The petition did not request that FDA establish requirements for the labeling of products manufactured with BPA. Therefore, this comment is outside the scope of the action requested by the petition, and FDA did not consider this comment.

F. The Amount of BPA Allowed in the Plastic Products

(Comment 6) One comment expressed the opinion that one way to determine if PC resins are not present in a plastic product is to measure the presence of BPA in the product. The comment suggested that, in addition to granting ACC's petition, FDA should set a limit of the amount of BPA found in the other suggested plastic products to 0.1 parts per billion.

(Response) The petition did not request that FDA establish limits for the amount of BPA in certain products. Therefore, this comment is outside the scope of the action requested by the petition, and FDA did not consider this comment.

IV. Conclusion

FDA reviewed the data and information in the petition and other available relevant material to evaluate whether the use of BPA-based PC resins in the manufacture of baby bottles and sippy cups has been completely and permanently abandoned. Based on the available information, the Agency concludes that these uses have been completely and permanently abandoned. Therefore, the regulations in 21 CFR part 177 should be amended as set forth in this document.

V. Public Disclosure

In accordance with § 171.1(h), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person (see FOR FURTHER INFORMATION CONTACT). As provided in § 171.1(h), the Agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

VI. Environmental Impact

The Agency has previously considered the environmental effects of this rule as announced in the notice of filing for FAP 1B4783 (77 FR 9608). No new information or comments have been received that would affect the Agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VII. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VIII. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections by (see DATES). Each objection must be separately numbered, and each numbered objection must specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested must specifically so state. Failure to request a hearing for any particular objection constitutes a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested must include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection constitutes a waiver of the right to a hearing on the objection. It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177--INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1580 is amended by adding paragraph (d) to read as follows:

§ 177.1580 Polycarbonate resins.

* * * * *

(d) Polycarbonate resins may be used in accordance with this section except in infant feeding bottles (baby bottles) and spill-proof cups, including their closures and lids, designed to help train babies and toddlers to drink from cups (sippy cups).

Dated: July 12, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-17366 Filed 07/16/2012 at 8:45 am; Publication Date: 07/17/2012]